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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,040	01/28/2004	David R. Fischell	MR3065-11	9612

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EXAMINER	
ROSENZWEIG, JASON	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,040	FISCHELL ET AL.	
	Examiner	Art Unit	
	Jason E. Rosenzweig	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-128* is/are pending in the application.

4a) Of the above claim(s) *41-128* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,23-26 and 28-40* is/are rejected.

7)☒ Claim(s) *22 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08132004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1-40 in the reply filed on 09/26/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

2. Claims 30 and 39 are objected to because of the following informalities: The claims are grammatically awkward. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 30 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 30 and 39, the term "constant level of perceptibility to the patient" is indefinite as this is dependent upon the patient and other outside factors such as the environment.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7, 25 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Ujhelyi (US 20030050566).

8. Regarding claims 1, 25, and 28, Ujhelyi discloses: A system for detection of cardiac events occurring in a human patient, comprising:

(a) at least two electrodes (Fig. 1, Elements 26, and 32) for obtaining an electrical signal from a patient's heart'

(b) an electrical signal processor (Fig 3, Element 128) electrically coupled to said electrodes for processing the electrical signal (Paragraph 14, Line 6); and,

(c) patient alarm means (Fig 2, Element 52; Paragraph 39, Ln. 2) with a internal audible alert module (Fig 2, Element 70) coupled to the electrical signal processor for generating an escalating sensory alarm signal received by the patient over a predetermined time period subsequent to the electrical signal processor detecting a cardiac event. Wherein Ujhelyi mentions tiered alerts, and by definition tier is "A rank or class" (Dictionary.com), thereby a tiered alert system could have alerts at different levels.

9. Regarding claim 2 and 3, Ujhelyi previously discloses: The system for detection of cardiac events occurring in a human patient (Paragraph 10) as recited in claim 1 wherein the cardiac event is coronary ischemia indicated by a change in the ST segment of the electrical signal which is part of the PQRST complex which includes a P-wave, corresponding to atrial depolarization, a QRS-complex, corresponding to ventricular depolarization, and a T-wave (Paragraph 4) which could also occur at a elevated heart rate.

10. Regarding claim 4, Ujhelyi previously discloses: The system for detection of cardiac events occurring in a human patient as recited in claim 1 wherein the cardiac event is an arrhythmia (see title).

11. Regarding claim 5, Ujhelyi discloses: The system for detection of cardiac events occurring in a human patient as recited in claim 4 wherein the arrhythmia is high heart rate (see abstract) otherwise known as Tachycardia (dictionary.com).

12. Regarding claim 6, Ujhelyi discloses: The system for detection of cardiac events occurring in a human patient as recited in claim 4 wherein the arrhythmia is low heart rate (see abstract) otherwise known as bradycardia (dictionary.com).

13. Regarding claim 7, Ujhelyi discloses: The system for detection of cardiac events occurring in a human patient as recited in claim 4 wherein the arrhythmia is an unsteady heart rate (see abstract) otherwise known as Atrial fibrillation (dictionary.com).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 1-4, are rejected under 35 U.S.C. 103(a) as being anticipated by Fischell (US 6272379) in view of Avitall (US 6171237).

17. Regarding claim 1, Fischell previously discloses: A system for detection of cardiac events occurring in a human patient, comprising:

(a) at least two electrodes (Fig. 1, Elements 13-16) for obtaining an electrical signal from a patient's heart'

(b) an electrical signal processor electrically coupled to said electrodes for processing the electrical signal (Fig 6); and,

(c) patient alarm means (Fig 6, Elements 48 and 71) coupled to the electrical signal processor for generating a sensory alarm signal received by the patient over a predetermined time period subsequent to the electrical signal processor detecting a cardiac event.

Fischell does not disclose specifically of an escalading alarm in element "b" of the above claim.

Avitall discloses a remote health monitoring system, which can be geared to monitoring congestive heart failure. Avitall does not disclose specifics regarding methods of obtaining an electrical signal from the patient's heart however he does specifically disclose of a method for automatically increasing the volume of an audible alarm until a manual reset action is taken (Col. 7, Ln. 23). It would be obvious to one of ordinary skill in the art to implement an escalating alarm based upon the teachings of Avitall in any remote health-monitoring device.

18. Regarding claim 2 and 3, Fischell in view of Avitall previously discloses: The system for detection of cardiac events occurring in a human patient as recited in claim 1, wherein the cardiac event is coronary ischemia indicated by a change in the ST segment of the electrical signal (Figure 6, Element 37) which could also occur at a elevated heart rate.

19. Regarding claim 4, Fischell in view of Avitall previously discloses: The system for detection of cardiac events occurring in a human patient as recited in claim 1 wherein the cardiac event is an arrhythmia which could be caused by a myocardial infarction (see abstract) since by definition Arrhythmia is "An irregularity in the force or rhythm of the heartbeat"(dictionary.com).

20. Claims 10-17,19-21,23,24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (US 6272379) in view of Avitall (US 6171237) as applied to claims 1-4 above, and further in view of Lebel (US 6571128).

21. Regarding claims 10--24, Lebel discloses an implantable infusion pump disclosing: both an audio alarm and a vibrator for alerting the patient or user of warnings and alarm conditions. The user has some control over the selection of audio alarm or vibration while the system can automatically switch from vibration to audio if the vibrational alarm is not responded to in a timely manner. The audio alarm is programmable to emit at different frequencies, at different volume levels, for different durations, and with different repetition patterns. These various alternatives are used to signal different conditions. The vibratory alarm is also programmable to go off for different durations and with differing repetition patterns. In alternative embodiments,

only one type of alarm may be used and it may be used with or without different frequencies, volumes, durations, or loudness. Lebel's device is not a system for detection of cardiac events however both Fischell and Avitall disclose devices which are used to detect various cardiac events. It would have been an obvious matter of design choice to one of ordinary skill in the art to combine the teachings of Fischell and Avitall in further view of Lebel to have a device, which provided various alarm signals in order to notify a user that cardiac events have been detected. Since applicant has not disclosed that choosing a particular signal pattern to alert the use solves any problem compared to the aforementioned methods of notifying a user it would appear that the invention would perform equally well with a signal or tone disclosed of by Lebel in the claimed in invention.

22. Regarding claims 25, and 26, Fischell in view of Avitall significantly disclose the claimed invention except for an escalating alarm signal originating from an implanted medical device. Lebel discloses a implanted medical device specifically a implantable infusion pump which includes an escalating internal alarm signal which can include a audible or vibration alert (Col 27, Ln. 48). It would be obvious to one of ordinary skill in the art to implement a system, which can vary alert tone and characteristics based on different events and responses from the user.

23. Claims 8-9, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ujhelyi in view of Ferek-Petric (5,076,272).

24. Regarding claims 8 and 9, Ujhelyi discloses a system for detection of cardiac events occurring in a human patient as recited in claim 1 wherein the cardiac event is an arrhythmia (see title). Ujhelyi specifically mentions detecting arrhythmia as an unsteady heart rate and the management of atrial fibrillation (see abstract) but he does not mention detecting the underling cause of the arrhythmia where it is the result of PVCs defined as premature ventricular contractions.
Ferek-Petric discloses an apparatus having a patient alarm for warning about a pacing malfunction, a pacing system failure, or potentially hazardous cardiac arrhythmias. But does not disclose of the number of electrodes used since his invention is only pertinent to the alarm means. Ferek-Petric specifically mentions detecting PVCs (Col 10, Ln. 35) and other arrhythmias. It would be obvious to one of ordinary skill in the art to modify Ujhelyi's disclosure in view of Ferek-Petric to include a counter to detect PVCs in order to supply further detail into the underlying cause of an arrhythmia.

25. Claims 25, 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ujhelyi in view of Amano (US 6,095,984).

26. Regarding Claims 25, and 28-29, Ujhely discloses a device and method of Arrhythmia Notification including a internal or external Audible Alert Module (Fig 2, Element 70), Vibration Module (Fig. 2, Element 68), and a remote display indicator (Fig 2, Element 66) where. Ujhely does not give specifics to the alarm signal however he does specify the use of tiered alerts (Paragraph 39, Line 2). It would have been an obvious matter of design choice to choose a multiplicity of alerting tones in order to alert

the user of a detected cardiac event, since applicant has not disclosed that his particular alerting tones solve any stated problem or is for any particular purpose and it appears that the invention would perform equally well with Ujhely's disclosed device.

27. Regarding claims 31-38 and 40, Ujhely in view of Amano significantly discloses the claimed invention of claim 25 as described in the above claim rejection. Both Ujhely (Paragraph 32) and Amano (Col 23, Ln. 66) disclose the use of a pager as an external alarm source. Ujhely discloses the use of a visual display (Fig. 2, Element 66). Ujhely does not implicitly state the order of alarm signals being initiated however it is inherent that a tiered alert system (Paragraph 39) is present and could be programmed to selectively notify multiple status indicator devices (Paragraph 34) in a specific order. It would be obvious to one of ordinary skill in the art to implement an external alarm signal generated by an external alarm system, where the external alarm signal being initiated at a preset time before the initiation of the escalating internal alarm signal in order to notify users of the cardiac event detection system.

28. Regarding claims 30 and 39, Ujhelyi in view of Amano discloses: A system for the detection of cardiac events occurring in a human patient as recited in claim 25 further including an external alarm signal generated by an external alarm system (see abstract) is of constant level of perceptibility to the patient. A constant level of perceptibility is dependent upon the individual however an external programmer could adjust the system such that the device can compensate for different users sensory abilities (Paragraph 41).

Allowable Subject Matter

29. Claims 22 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

30. Regarding claim 22, a exhaustive search of prior art did not reveal any prior art which discloses a time interval between alerting signals which progressively decreases over time.

31. Regarding claim 27, although some of the references disclose the use of a electrical tickle none disclose it's use in combination with a specific signal as disclosed in claim 25.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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